K133367

510(k) Summary

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510(k) SPONSOR / MANUFACTURER: Custom Orthopaedic Solutions, Inc.
A subsidiary of Cleveland Clinic
10000 Cedar Avenue
Cleveland, Ohio 44106

CONTACT PERSON: Justin Baker, PhD
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DATE PREPARED: 16-September-2013

TRADE NAME: OrthoVis Preoperative Plan

COMMON NAMES: Preoperative Planning tool

Product	Product Code	Regulation and Classification Name	Device Class
OrthoVis Preoperative Plan	**LLZ**	**21 CFR 892.2050 Picture Archiving & Communications System**	**II**

PREDICATE DEVICES:

Custom Orthopaedic Solutions Glenoid IRIS (K123122)
Materialise N.V. SurgiCase (K073449)

DEVICE DESCRIPTION:

The OrthoVis Preoperative Plan is a preoperative plan document that is created in OrthoVis software. A patient CT scan is loaded into OrthoVis software and the desired bony anatomy can be separated and segmented with OrthoVis tools, allowing extracted and segmented bones (e.g., scapula, humerus) to be virtually implanted with shoulder replacement implants. OrthoVis currently is used only with the DePuy Global APG glenoid, DePuy Global StepTech, and DePuy Delta Xtend components for total shoulder arthroplasty. OrthoVis can then produce a preoperative plan document (.pdf file), the OrthoVis Preoperative Plan, that contains text, images, and in electronic format, a rotatable 3D model(s) of the implanted component and bone. This preoperative plan document is labeled, via a watermark, as unapproved until the ordering surgeon approves the plan, at which point such labeling is removed and the final plan provided to the ordering surgeon.

INTENDED USE AND INDICATIONS:

The OrthoVis Preoperative Plan is a preoperative plan document created via the OrthoVis software that facilitates accurate preoperative planning and intraoperative placement of the glenoid component in total shoulder replacement. The OrthoVis Preoperative Plan is indicated for use with the DePuy Global AP™ Shoulder glenoid, Global Shoulder StepTech™ Anchor Peg glenoid, or Delta Xtend™ Reverse Shoulder metaglene components.

The indications for use of the DePuy shoulder systems with which the OrthoVis Preoperative Plan is intended to be used are the same as those described in 510(k) K123122.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The OrthoVis Preoperative Plan is substantially equivalent to the Glenoid IRIS and Materialise SurgiCase system in function, intended use, input, and sterility. The OrthoVis Preoperative plan is substantially equivalent in function for in that the subject and predicate devices are based off patient specific CT image data that allows segmentation of desired bony anatomy. In all of the systems the purpose of the subject and predicate devices is to provide a preoperative plan to influence surgical planning and accuracy. The Materialise SurgiCase system is also able to use MRI imaging data; however, we do not believe this difference impacts the substantial equivalence of the OrthoVis Software & OrthoVis Preoperative Plan to the Materialise SurgiCase system. The subject device in this 510(k) is also substantially equivalent to the Glenoid IRIS predicate device because the OrthoVis Software & OrthoVis Preoperative plan is used with the same DePuy implant systems as the Glenoid IRIS system. The Materialise SurgiCase system allows .stl files (cutting guides, etc.) to be loaded into the preoperative planning environment and the location of the loaded geometry is able to be evaluated for preoperative planning purposes. In this case, both the subject and predicate devices allow preoperative evaluation of implant (model .stl files) size and placement as well as improved visualization of the segmented bones that would otherwise be obscured by surgical exposure constraints. The OrthoVis Preoperative Plan is substantially equivalent to the Glenoid IRIS in that both are used to preoperatively plan the location of the 2.5 mm guide pin for glenoid implant preparation. Finally, the subject and predicate devices are substantially equivalent because in all three systems the surgeon is required to approve the final preoperative plan.

The OrthoVis Preoperative Plan is substantially equivalent to the Glenoid IRIS system and Materialise SurgiCase system in its intended use. The intended use of the OrthoVis Software & OrthoVis Preoperative Plan is identical to that of the Glenoid IRIS system and differs only in that the Glenoid IRIS system contains other components (rapid prototyped bone models and a separate instrument). The intended use of the OrthoVis Preoperative Plan and the Materialise SurgiCase system is similar in that both are intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner and that both are intended to be used as preoperative planning software for simulating/evaluating implant placement and surgical treatment options. There are minor differences between the Materialise SurgiCase system and the OrthoVis Preoperative plan, one being that Materialise SurgiCase may use MRI data. Lastly, the OrthoVis Preoperative Plan is more specific than the Materialise SurgiCase system as it uses the actual implant files for three DePuy shoulder replacement systems and the SurgiCase system is not limited to just the shoulder or to specific implant systems. We believe that just because the OrthoVis Preoperative Plan is more focused on a specific joint and implant systems does not alter its substantial equivalence to the predicate devices.

The OrthoVis Preoperative Plan is substantially equivalent to the predicate devices because it shares the same input modality as the predicate devices. Both the subject and predicate devices use patient CT images as input. All of the systems use the CT images to create a virtual model of the segmented, desired bony anatomy. Both the OrthoVis Preoperative Plan and the Glenoid IRIS system generate a 3D virtual model in the OrthoVis software and capture images that the surgeon may use for visual reference in preoperative planning and carrying out the planned surgery. Both the subject device and predicate

devices must have the preoperative plans reviewed and approved by the ordering surgeon prior to delivery of the final device product. The differences between the subject and predicate systems are minor. First, the SurgiCase system is able to use CT images, 2D radiographs, as well as MRI. Second, the Glenoid IRIS system and Materialise SurgiCase system use the preoperative plan and images to create instruments (bone models or patient specific cutting guides) that aid in carrying out the plan. In this case, the OrthoVis Preoperative Plan does not go beyond creating visual reference images for carrying out the plan; however, we feel that these differences are outweighed by the substantial similarities between the systems and thus do not make the OrthoVis Preoperative Plan not substantially equivalent.

Finally, the OrthoVis Preoperative Plan is substantially equivalent to the predicate devices because in all systems the preoperative plan or software for creating the preoperative plan is provided non-sterile. While in the Glenoid IRIS system there are extra components that are provided sterile, the OrthoVis Preoperative Plan as a stand-alone product does not make use of these extra components.

Non-Clinical Testing

The following testing was performed to demonstrate substantial equivalency of the OrthoVis Preoperative Plan to the predicate devices.

- Software verification and validation
- Dimensional validation
- Sawbones study

The software verification and validation studies were performed to show that bones segmented in the OrthoVis software were segmented accurate to their actual size. Furthermore, the OrthoVis Software for producing the OrthoVis Preoperative Plan was verified and validated for quality purposes according to the guidance on Software in Medical Devices. In this case, the OrthoVis Preoperative Plan software is substantially equivalent to the predicate devices in that all the systems were required to undergo similar software verification and validation activities to ensure accuracy and quality in the products intended use and function.

The dimensional validation performed on the software showed that known lengths of actual CT scanned objects could be accurately measured and portrayed within the OrthoVis software.

The Sawbones study was a bench testing study of simulated use of the OrthoVis Software & Preoperative Plan as well as of the full Glenoid IRIS system. While the full Glenoid IRIS system is not pertinent to this 510(k), an intermediate aspect of this study evaluated the effect of the OrthoVis Preoperative Plan as a stand-alone tool in helping various surgeons to accurately achieve a preoperatively planned implant location in mock total shoulder arthroplasty procedures. Three different surgeons performed the study on two instances each of 9 different pathologies (ranging from mild deformity to severe). Results of the study showed that the OrthoVis Preoperative Plan improved accuracy of guide pin placement in version by 4.5° (±1° s.d.)($p<0.001$) compared to standard of care instruments, inclination improved by 3.3° (±1.3° s.d.)($p=0.013$), and pin placement by 0.4 mm (±0.2 mm)($p=0.042$).

Conclusion

The non-clinical testing performed for the OrthoVis Preoperative Plan product shows that the OrthoVis Software and the Preoperative Plan is able to accurately perform its intended use and function. The Sawbones study shows that the OrthoVis Preoperative Plan does indeed aid as a visual reference for simulating/evaluating surgical treatment options for total shoulder arthroplasty. In conclusion, as discussed in this section, the OrthoVis Preoperative Plan is substantially equivalent to the Glenoid IRIS and

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Materialise SurgiCase predicate devices in function, use and intended-use, input, surgical approval, and sterility. While the systems are not exactly the same, the aforementioned similarities make the subject device substantially equivalent to the predicate devices more than the differences make the devices not substantially equivalent. The differences between the systems are typically ways in which one or both of the predicate devices goes beyond what the OrthoVis Preoperative Plan by itself provides, but do not negate the substantial similarities that the subject and predicate devices all share.

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A. Type of Submission
510(k)
Original Submission
Traditional

B. Applicant or Sponsor

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Establishment Number:	3010197296
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D3. Reason For Submission – 510(k)
OrthoVis Preoperative Plan as a stand-alone product (currently part of the Glenoid IRIS, K123122).

E. Additional Information on 510(k) Submission
Product codes of devices to which substantial equivalence is claimed: LLZ
510(k) summary attached

510(k) Number	Trade or Proprietary or model name	Manufacturer
1. K123122	Glenoid Intelligent Reusable Instrument System	Custom Orthopaedic Solutions
2. K073449	Materialise SurgiCase system	Materialise

F. Product Information – Applicable to All Applications
Common or usual name or classification name: Picture Archiving & Communications System (Image Processing System)
Trade name or proprietary or model name: OrthoVis Preoperative Plan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Custom Orthopaedic Solutions
% Justin J. Baker, Ph.D.
Regulatory & Quality Manager
10000 Cedar Avenue
CLEVELAND OH 44106

Re: K133367
Trade/Device Name: Orthovis Preoperative Plan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 12, 2013
Received: November 1, 2013

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

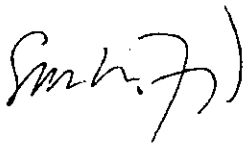
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133367

Device Name: OrthoVis Software & Preoperative Plan

Indications for Use:

The OrthoVis Preoperative Plan is a preoperative plan document created via the OrthoVis software that facilitates accurate preoperative planning and intraoperative placement of the glenoid component in total shoulder replacement. The OrthoVis Software and resulting Preoperative Plan is indicated for use with the DePuy Global APTM Shoulder glenoid, Global Shoulder StepTechTM Anchor Peg glenoid, or Delta XtendTM Reverse Shoulder metaglene components.

The indications for use of the DePuy shoulder systems with which the OrthoVis Preoperative Plan is intended to be used are the same as those described in 510(k) K123122.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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